

# NUTRAMEDIX

XFACTOR  PRODUCTOS GARCIA INC.

16 23 '98 APR 28 P4:01

Monday, April 13, 1998

Food and Drug Administration  
Office of Special Nutritional (HFS-450)  
Center for Food Safety and Applied Nutrition  
200 C Street, SW  
Washington, DC 20204

RECEIVED  
4/21/98

Dear Sirs,

Notice is hereby given pursuant to the requirements of section 403(r) (6)(21 U. S. C.343(r)(6) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR 101.93, that Nutramedix Inc., of 212 N. US Hwy. One, Suite 17 Tequesta, FL 33469 within the past 30 days commenced marketing a dietary supplement bearing the following statement(s) on the label and/or in the labeling:

**PRODUCT NAME: BRAINx**

**TEXT OF CLAIMS FOR PRODUCT:**

**A PHYTO-NUTRIENT SUPPLEMENT FORMULATED TO MAINTAIN MENTAL PERFORMANCE, CONCENTRATION AND MEMORY.**

BRAINx - a synergistic plant-based formula designed to maintain cognitive performance of the brain. This formula promotes circulation of blood and oxygen to the Brain by providing both well-known and recently discovered phyto-nutrients.

**INDIVIDUAL PRODUCT INGREDIENTS:**

**Rosemary (flower, leaves)**

Since ancient Greece rosemary has been know as the "herb of remembrance." Supplies carvacrol and other compounds.

**Lemon Balm (leaves)**

A member of the mint family, lemon balm contains volatile oils that may maintain normal acetylcholine levels

**Gotu Kola (nuts, roots, seeds)  
Standardized Dry Extract**

It is sometimes referred to as food for the brain. It has magnesium in an easily assimilated form.

97 S - 0162

212 North US Highway One, Suite # 17 • Tequesta, Florida 33469 USA  
Telephone: 561-745-2917-800-730-3130 • Telefax: 561-745-3017  
<http://www.nutramedix.com>

58569  
LET 1538

**Ginkgo Biloba (leaves)  
Standardized Dry Extract**

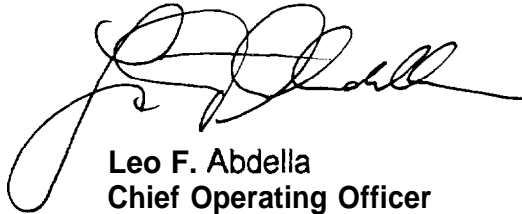
**Help to support normal brain and memory functions. Supports the vascular system, the body's vast network of blood vessels that delivers blood & oxygen.**

**Crystalloid Electrolytes  
(minerals)**

**Science has now recognized the necessity of electrolytes for maintaining the body's complete nutrient delivery system.**

**The Undersigned certifies that the information contained in this notice is complete and accurate and that Nutramedix Inc., has substantiation that the statements are truthful and not misleading.**

**Sincerely,**

A handwritten signature in black ink, appearing to read 'Leo F. Abdella', with a long, sweeping horizontal stroke extending to the right.

**Leo F. Abdella  
Chief Operating Officer**